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NORTH DISTRICT OF CALIFORNIA

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

KAW

CV 23 0781

UNITED STATES OF AMERICA *ex rel.*
WAYNE HARRINGTON,

Plaintiff,

v.

SANOFI PASTEUR, INC., a Delaware
corporation; MERCK SHARP & DOHME,
LLC, a New Jersey Limited Liability
Company; inclusive,

Defendants.

Case No..

FILED UNDER SEAL PURSUANT
TO 31 U.S.C. § 3730 subd. (b) (2)

DEMAND FOR JURY TRIAL

1 On behalf of the United States of America pursuant to the United States False
2 Claims Act (“FCA”), 31 U.S.C. §§ 3729-33, Relator WAYNE HARRINGTON
3 (“Relator”) files this *qui tam* Complaint for treble damages and civil monetary
4 penalties against Defendants SANOFI PASTEUR, INC. (“SANOFI”) and MERCK
5 SHARP & DOHME, LLC (“MERCK,” collectively referred to as “Defendants”).
6 This action arises from Defendants’ scheme to defraud the United States
7 Department of Health and Human Services (“HHS”) by intentionally hacking into a
8 government-run website and illicitly obtaining private sales data to monopolize the
9 childhood vaccine market and thereby gain an unfair advantage over the Secretary
10 of HHS in negotiating Federal nation-wide purchasing contracts.

11 On an annual basis, the HHS Secretary negotiates and enters into purchasing
12 contracts directly with pharmaceutical manufacturers to supply inventory for the
13 Vaccines for Children (“VFC”) Program, a federal entitlement program that
14 provides vaccines to children from low-income communities free of charge.
15 Through the VFC Program, HHS distributes vital vaccines to those in need by and
16 through the individual States. The States then provide the vaccines to private and
17 public healthcare providers that have successfully registered as VFC providers to
18 administer to the children in their communities.

19 In California, VFC providers place orders for childhood vaccines, in
20 sufficient quantities to service their communities, through California Department of
21 Public Health’s VFC website, EZIZ.org. To access EZIZ.org, each VFC provider is
22 required to login with user-specific credentials. Pharmaceutical companies, like
23 Defendants, are not provided with login credentials and are not authorized to access
24 the California VFC provider ordering portals.

25 Nevertheless, Defendants furnish their sales representatives, called “Vaccine
26 Specialists,” with the login credentials of every California VFC provider.
27 Defendants have instructed their sales representatives in Northern California to use
28 the VCF provider login credentials to access their ordering history, specifically to

1 identify the VFC providers who are ordering products manufactured by competing
2 pharmaceutical companies.

3 Since approximately 2021, through the unauthorized use of state data,
4 Defendants have targeted aggressive sales efforts to “convert” VFC providers in
5 Northern California from the use of competitor products to their newly developed
6 and recently FDA-approved six-in-one vaccine, Vaxelis, along with their portfolio
7 of other drugs. Defendants seek to monopolize the childhood vaccine market by and
8 pushing out its VFC-approved competition, thereby gaining undue advantage over
9 the HHS Secretary in VFC contract negotiations. Defendants’ conduct constitutes
10 fraud against the Federal government under the following theories: (1) fraud in the
11 inducement, (2) false certification and (3) submission of factually false claims to
12 defraud the government.

13 In support of these claims, Relator alleges as follows:
14

15 **I. INTRODUCTION.**

16 1. This is an action brought by Plaintiff/Relator, WAYNE
17 HARRINGTON, an individual, on behalf of the United States of America, to
18 recover damages and civil penalties against Defendants SANOFI PASTEUR, INC.
19 (“SANOFI”) and MERCK SHARP & DOHME, LLC (“MERCK,” collectively
20 referred to as “Defendants”) pursuant to the FCA, 31 U.S.C. §§ 3729-33.

21 2. The Vaccines for Children (“VFC”) Program provides necessary
22 vaccines to children whose families or guardians are unable to afford them.

23 3. Every vaccine that is made available through the VFC Program has
24 been recommended by the Advisory Committee on Immunization Practices
25 (“ACIP”) to protect infants, young children, and adolescents from sixteen deadly
26 diseases that the country hopes to eradicate entirely through modern medicine.

27 4. Funding for the VFC Program is approved by the Office of
28 Management and Budget (“OMB”) and allocated through the Centers for Medicare

1 & Medicaid Services (“CMS”) to the Department of Health and Human Services
2 (“HHS”), specifically the Centers for Disease Control and Prevention (“CDC”).
3 HHS, via the CDC, purchases childhood vaccines at a discounted price directly
4 from pharmaceutical manufactures and distributes them to grantees—state public
5 health departments and certain local and territorial public health agencies—which
6 in turn distribute them at no charge to those private physicians’ offices and public
7 health clinics registered as VFC providers.

8 5. The State of California distributes VFC vaccines through the
9 Immunization Branch of the California Department of Public Health (“CDPH”).
10 CDPH provides training modules, educational resources, and management tools,
11 specific to the storage and administration of childhood vaccines, to VFC providers
12 through a website, EZIZ.org (“EZIZ”). EZIZ additionally hosts a secure portal for
13 California VFC providers to order inventory of childhood vaccines for their clinics
14 and offices. Login credentials unique to each VFC provider are required to access
15 the ordering portal. The EZIZ ordering portal displays the provider’s ordering
16 history, including the brand, quantity, and frequency of orders.

17 6. Since as early as 2021, Defendants have illicitly hacked into the EZIZ
18 provider portal by knowingly using the login credentials of nonconsenting VFC
19 providers throughout California—indeed intentionally and fraudulently
20 impersonating VFC providers.

21 7. Defendant SANOFI, in collusion with Defendant MERCK, provides
22 its sales representatives with the login credentials of VFC providers by zip code,
23 with the specific instruction to develop targeted sales strategies to convert
24 customers relying primarily on competitor products.

25 8. Defendants intentionally seek to use the illegally obtained government
26 data to increase its share of the childhood vaccine market. As a result of
27 Defendants’ anti-competitive practices, they are putting the Federal government at a
28 bargaining disadvantage in annual VFC purchasing negotiations.

9. Defendants have tilted the odds in their favor, such that HHS has been and will continue to be compelled to pay higher prices for important childhood vaccines than it would otherwise pay if there were fair competition among several drug manufacturers.

10. In short, Defendants hacked into a state-run website and instructed its employees to use private purchasing information for the purpose of establishing a dominant share of the vaccine market. By engaging in such illicit activities, Defendants generated additional sales, and, more importantly increased its bargaining power with the federal government, and thereby causing HHS to enter into unfair contracts at a higher price.

II. JURISDICTION AND VENUE.

11. This is a civil action arising under the laws of the United States to redress violations of 31 U.S.C. §§ 3729-3730. This Court has subject matter jurisdiction over this action: (i) pursuant to 31 U.S.C. §§ 3732, which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730; (ii) pursuant to 28 U.S.C. § 1331, which confers federal subject matter jurisdiction; and (iii) pursuant to 28 U.S.C. § 1345, because the United States is a plaintiff.

12. This Court has personal jurisdiction over Defendant SANOFI pursuant to 31 U.S.C. § 3732(a) because Defendant SANOFI can be found, resides, or transacted business in this district, or an act proscribed by 31 U.S.C. § 3729 occurred in this district. In this district, Defendant SANOFI has (1) falsely certified its compliance with all federal laws in contracting with the federal government; (2) made, or caused to be made or used, false or fraudulent records to get false or fraudulent claims paid or approved by the Federal Government of the United States.

13. This Court has personal jurisdiction over Defendant MERCK pursuant to 31 U.S.C. § 3732(a) because Defendant MERCK can be found, resides, or

transacted business in this district, or an act proscribed by 31 U.S.C. § 3729 occurred in this district. In this district, Defendant MERCK (1) falsely certified its compliance with all federal laws in contracting with the federal government; and (2) made, or caused to be made or used, false or fraudulent records to get false or fraudulent claims paid or approved by the Federal Government of the United States.

14. Venue is proper in this District under 31 U.S.C. § 3732(a) and 28 U.S.C § 1391 because Defendants can be found, reside in, and transact business in this District, and because Defendants committed acts within this District that violate 31 U.S.C. § 3729.

III. PARTIES.

A. Plaintiff/Relator WAYNE HARRINGTON.

15. Plaintiff/Relator WAYNE HARRINGTON, an individual, brings this action on behalf of himself and the United States pursuant to 31 U.S.C. § 3730(b)(1).

16. Relator is and, at all times relevant to the allegations herein, has been a resident of the State of California.

17. From June 2013 through January 2023, Relator was employed by Defendant SANOFI as a sales representative. From June 2013 to September 2019, Relator sold diabetes medications through SANOFI's subsidiary, Sanofi-Aventis. From September 2019 to January 2023, Relator worked in vaccine sales and was responsible for matching or surpassing annual sales the in his "sales territory," which encompasses the cities of Alameda, Contra Costa, and Tracy in the State of California.

18. To the extent that there has been a public disclosure of the fraud alleged herein, it is unknown to Relator. Relator is, nevertheless, the original source of the information upon which the allegations in this Complaint are based, pursuant to 31 U.S.C. § 3630(e)(4).

1 19. Relator is also the original source of the information pertaining to
 2 Defendants' business practices described herein, including Defendants willfully
 3 instructing its employees to fraudulently access a state-run VFC provider portal to
 4 obtain private vaccine ordering data. By doing so, Defendants sought to and are in
 5 the process of establishing an unlawful monopoly to the disadvantage of its largest
 6 public customer, HHS.

7 20. Relator has voluntarily disclosed to the United States substantially all
 8 the information on which the allegations and transactions described herein are
 9 based as well as voluntarily provided the information to the Federal Government
 10 concurrently with the filing of this action under 31 U.S.C. § 3730(b).

11 **B. Defendant SANOFI PASTEUR, INC.**

12 21. Defendant Sanofi Pasteur, Inc. ("SANOFI") is a Delaware corporation
 13 that manufactures pharmaceuticals, including vaccines. SANOFI is and, at all times
 14 relevant to the allegations herein, a corporation, organized and existing by virtue of
 15 the laws of the state of its incorporation. SANOFI's headquarters are presently
 16 located at 1 Discovery Drive, Swiftwater, Pennsylvania 18370.

17 22. As part of its sales and marketing operations, SANOFI has divided the
 18 country into five "sales regions," each lead by a Regional Sales Director. Each
 19 "sales region" is divided into approximately six to seven "sales districts," each
 20 headed by a District Sales Manager. Each "sales district" is made up of
 21 approximately nine to ten "sales territories," which can comprise of several cities
 22 and are worked by teams of sales representatives.

23 23. The District Sales Managers are responsible for achieving sales quotas
 24 for all products that they have been tasked with selling in that district. Each District
 25 Sales Manager leads a team of sales representatives. The District Sales Manager
 26 hires and trains his or her team of sales representatives, and ensures that they
 27 achieve the sales goals for all "sales territories."

28 24. SANOFI manufactures childhood vaccines including Pentacel,

1 Quadracel, Adacel, MenQuadfi, and Menactra. Childhood vaccines can be
2 administered as singular vaccines (one vaccine per injection) or as combined
3 vaccines (multiple vaccines delivered in one injection), according to a schedule
4 based on the age of the patient. The trend in the childhood vaccine industry has
5 been to develop a mechanism for delivering more vaccines in a single shot.

6 25. In 2018, SANOFI, along with its partner Defendant MERCK SHARP
7 & DOHME, LLC, received FDA-approval for the childhood first hexavalent (six-
8 in-one) vaccine, Vaxelis. The FDA approved Vaxelis as a three-dose series for
9 children as young as six-weeks old until they turn five-years-old.

10 26. In June 2019, the Advisory Committee on Immunization Practices
11 issued a resolution to add Vaxelis as a pre-approved drug for the VFC program,
12 although it would not be immediately available for distribution.

13 27. In 2021, Vaxelis became available for sale and distribution throughout
14 the United States.

15 **C. Defendant MERCK SHARP & DOHME, LLC.**

16 28. Defendant MERCK SHARP & DOHME, LLC (“MERCK”) is a New
17 Jersey Limited Liability Company that manufactures vaccines. MERCK’s
18 headquarters are presently located at 126 East Lincoln Avenue, Rahway, New
19 Jersey 07065.

20 29. In 1991, MERCK entered into a partnership with SANOFI for the
21 development, manufacturing, and marketing of individual and combination
22 vaccines.

23 30. In 2018, MERCK and Defendant SANOFI, received FDA-approval for
24 the first childhood hexavalent (six-in-one) vaccine, Vaxelis. The FDA approved
25 Vaxelis as a three-dose series for children from six-weeks to five-years-old.

26 31. In June 2019, the Advisory Committee on Immunization Practices
27 issued a resolution to add Vaxelis as a pre-approved drug for the VFC program,
28 although it would not be immediately available for distribution.

1 32. In 2021, Vaxelis became available for sale and distribution throughout
2 the United States.

3
4 **IV. THE VACCINES FOR CHILDREN PROGRAM.**

5 **A. The Federal Program.**

6 33. The Vaccines for Children (“VFC”) Program is a federal entitlement
7 program that provides free, life-saving pediatric vaccines to children who otherwise
8 would not be vaccinated due to an inability to pay. Expenditures for the vaccines
9 and for the program’s administration are financed by Medicaid. The program was
10 created by the Omnibus Budget Reconciliation Act on August 10, 1993, and is now
11 known as Section 1928 of the Social Security Act.

12 34. By establishing the VFC Program, Congress intended to imposed a
13 new requirement of State Medicaid plans “to provide for a program for the
14 distribution of pediatric vaccines to program-registered providers for the
15 immunization of vaccine-eligible children in accordance with section 1928 [42
16 USCS § 1396s].” 42 USCS § 1396a(a)(62). Accordingly, under the Social Security
17 Act, each state must establish a program of distribution of free vaccines to certain
18 vaccine-eligible children. 42 USCS § 1396s(a)(1)(A).

19 35. The VFC Program enables the Federal government to purchase
20 childhood vaccines to distribute to each State. 42 USCS § 1396s(a)(2). States must
21 make these vaccines available to all children who seek them, and can do so by
22 allowing public and private health care providers to request specific quantities of
23 vaccines to service their communities. 42 USCS 1396s(c)(1). Neither vaccine-
24 eligible children nor health care providers administering the vaccines may be
25 charged for the cost of the vaccines. 42 USCS 1396s(a)(1).

26 36. On an annual basis, the Secretary of the Department of Health and
27 Human Services (“HHS”) negotiates and enters into contracts purchasing contracts
28 with pharmaceutical manufacturers to supply the VFC Program. 42 USCS §

1 1396s(d).¹ The States may also obtain additional quantities of pediatric vaccines
 2 through separate purchasing contracts with the manufactures, if certain conditions
 3 are met. 42 USCS § 1396s(d)(4)(B).

4 37. Importantly, because Congress recognized that “the Federal market
 5 share in the vaccine industry will be increased under the new program,” the Social
 6 Security Act expressly provides that “the [HHS] Secretary shall, as appropriate,
 7 enter in a contract [] with *each* manufacturer for the vaccine that meets the terms
 8 and conditions of the Secretary for an award of such a contract.” Omnibus Budget
 9 Reconciliation Conference Report - 139 Cong Rec S 1068; 42 USCS § 1396s(d)(7)
 10 (emphasis added). Congress adopted this provision explicitly to: (1) “ensure that
 11 each manufacturer obtains an *appropriate share* of the contract”; and (2) “assure
 12 that Federal contracts under the program encourage *competition, innovation, and*
 13 *efficiency*.” Omnibus Budget Reconciliation Conference Report - 139 Cong Rec S
 14 1068 (emphasis added). In sum, the HHS Secretary enters into purchasing contracts
 15 with multiple pharmaceutical manufacturers for the express purpose of encouraging
 16 and protecting fair market competition.

17 38. At the national level, the VFC Program is administered by HHS
 18 through the Centers for Disease Control and Prevention (“CDC”) and the National
 19 Center for Immunization and Respiratory Diseases. At the state level, the VFC
 20 Program may be administered by the State’s department of health or another
 21 designated agency. 42 USCS § 1396s(a)(1).

22 **A. The California Program.**

23 39. California has a public interest in ensuring “a means for the eventual
 24 achievement of total immunization of appropriate age groups against [] childhood
 25 diseases.” Cal. Health & Safety Code § 120325.

26 40. The California VFC Program, which is managed by the Immunization
 27

28 ¹ A “manufacturer” is any corporation, organization, or institution, whether public or private, that manufactures, imports, processes, or distributes under its label any pediatric vaccine. 42 USCS § 1396s(h).

1 Branch of the California Department of Public Health (“CDPH”), has enrolled over
2 4,000 VFC provider sites since 1995.

3 41. To become an authorized provider, the private or public healthcare
4 provider must complete a Federal VFC Provider Agreement, in which the provider
5 expressly agrees to operate within the VFC program in a manner intended to avoid
6 fraud or abuse, consistent with “fraud” and “abuse” as defined in the Medicaid
7 regulations at 42 CFR § 455.2. Once approved, the VFC provider receives a unique
8 VFC Provider Identification Number (“PIN”).
9

10 42. California VFC providers order vaccine inventory from CDPH through
11 California’s VFC Program Provider website, EZIZ.org (“EZIZ”). To access the
12 EZIZ ordering portal, a VFC provider must login to the website using his or her
13 unique VFC PIN. A person or entity who is not actively enrolled in the California
14 VFC Program is not permitted to view, access, or engage with the EZIZ provider
15 portal.
16

17 **V. THE FEDERAL FALSE CLAIMS ACT.**

18 43. The Federal False Claims Act (“FCA”) reflects Congress’s intent to
19 “enhance the Government’s ability to recover losses as a result of fraud against the
20 Government.” S. Rep. No. 99-345, at 1 (1986), available at 1986 U.S.C.C.A.N.
21 5266. As relevant here, the FCA establishes civil penalties and treble damages
22 liability to the United States for an individual or entity that:

23 (A) knowingly presents, or causes to be presented, a false or
24 fraudulent claim for payment or approval; or

25 (B) knowingly makes, uses, or causes to be made or used, a false
26 record or statement material to a false or fraudulent claim . . .

27 31 U.S.C. § 3729(a)(1).
28

1 44. Under the FCA, the terms “knowing” and “knowingly”

2 (A) means that a person, with respect to information—

3 (i) has actual knowledge of the information;

4 (ii) acts in deliberate ignorance of the truth or falsity of the
5 information; or

6 (iii) acts in reckless disregard of the truth or falsity of the
7 information; and

8 (B) requires no proof of specific intent to defraud.

9 31 U.S.C. § 3729(b)(1).

10
11 **VI. DEFENDANTS’ VIOLATION OF THE FALSE CLAIMS ACT.**

12 45. Relator alleges, based upon Relator’s employment with SANOFI and
13 first-hand knowledge of Defendants’ unauthorized access of vaccine ordering data
14 from California’s state-run VFC provider portal, that Defendants made knowingly
15 false material statements and/or engaged in fraudulent conduct that caused the
16 federal government to enter into purchasing contract with Defendants for childhood
17 vaccines under the VFC program. By knowingly seeking to contract and actively
18 contracting with HHS under false or fraudulent pretenses, Defendants defrauded the
19 United States for monies, in violation of laws and regulations applicable to such
20 claims. Further, Defendants illegal use of vaccine data to fraudulently increase the
21 market share of their product constitutes submission of factually false claims to the
22 government.

23 46. Since September 2019, Relator has worked as a sales representative in
24 SANOFI’s vaccine division, selling Pentacel, Quadracel, Adacel, MenQuadfi, and
25 Menactra to VFC providers in Northern California.

26 47. In Quarter 3 of 2021, Vaxelis was introduced to the market as the first
27 six-in-one combination childhood vaccine. In addition to SANOFI’s other
28 childhood vaccines, Relator was tasked at this time with also selling Vaxelis to

VFC providers in his “sales territory.”

48. Prior to Vaxelis, the most vaccines that could be delivered in a single shot was five – Pentacel (manufactured by SANOFI) and Pediarix (manufactured by GlaxoSmithKlein Biologicals (“GSK”). From no later than September 2019 to the present, GSK’s Pediarix has been the highest selling and most widely used childhood vaccine in California. Since December 2021, Pediarix has constituted more than 51% of the childhood vaccine market share.

49. As part of its regular sales endeavors, SANOFI had and continues to have access to “DDD Reports,” which are SANOFI’s internal reports showing the purchasing history of private parties who ordered vaccine dose directly from SANOFI.

50. SANOFI also purchases CDC Public Provider Look Up Reports (“CDC Reports”), which show zip-code-level purchasing data, *i.e.*, the number of doses of different vaccines purchased in each zip code. The CDC Reports do not show the ordering history of specific VFC providers, and thus, does not tell SANOFI which providers prefer GSK products over its own.

CDC Zip Code Analysis Dossier Detailed Zip Code Rolling 12																			AA		🔍	
Current Rolling 12 Months																						
Market				TEAP				FOUO														
				Brand / CDC		Brand		Brand		Brand		Brand		Brand		Brand		Brand		Brand		
				DDO	ADACEL	ECOSERIF	IPOL	KINIKIT	FEDIASIR	Pentacel	Quadracel	Vaxelis	DAPTACEL	INFLANZ								
Zip	Division	Territory	State	CDC City	Doses	Share	Doses	Share	Doses	Share	Doses	Share	Doses	Share	Doses	Share	Doses	Share	Doses	Share		
92027	KSW	KSW02	CA	LOS ANGELES	1,465	72.3%	820	29.7%	650	10.2%	1,250	15.3%	1,120	33.2%	225	3.5%	589	9.3%	920	18.0%		
92034	KSW	KSW02	CA	LOS ANGELES	670	100.0%	0	0.0%	120	5.1%	510	22.0%	1,700	72.3%	0	0.0%	0	0.0%	608	6.4%		
92035	KSW	KSW02	CA	LOS ANGELES	75	100.0%	0	0.0%	50	31.9%	0	0.0%	0	0.0%	195	65.5%	0	0.0%	1816	18.16%		
92041	KSW	KSW02	CA	LOS ANGELES	120	100.0%	0	0.0%	72	17.5%	48	33.0%	152	56.7%	0	0.0%	0	0.0%	1505	2.0%		

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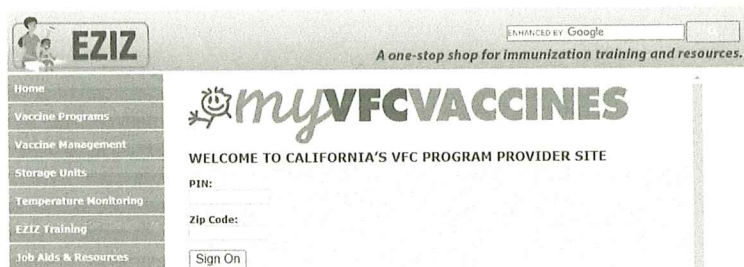
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51. The CDC Report also provides a list of each VFC provider within each zip code. Each VFC provider is identified with a specific account number.

52. From September 2019 through March 2022, Relator and other sales representatives used the DDD Reports and CDC Reports to form a general understanding of the purchasing trends within each zip code of his Sales Territory. However, neither Relator nor his colleagues actually knew which specific VCF providers historically and reliably purchased GSK drugs over SANOFI's drugs. Thus, just as with SANOFI's competitors, Relator and other sales representatives were required to spend a great deal of resources to visit all VCF providers in each zip code to determine their purchasing preferences and to potentially sell them their products.

53. In or around April 2022, James Dan was promoted to District Sales Manager and became Relator's direct supervisor. Beginning at this time, Dan instructed, encouraged, and enabled Relator and other members of the Northern California district sales team to hack into to the EZIZ provider portal.

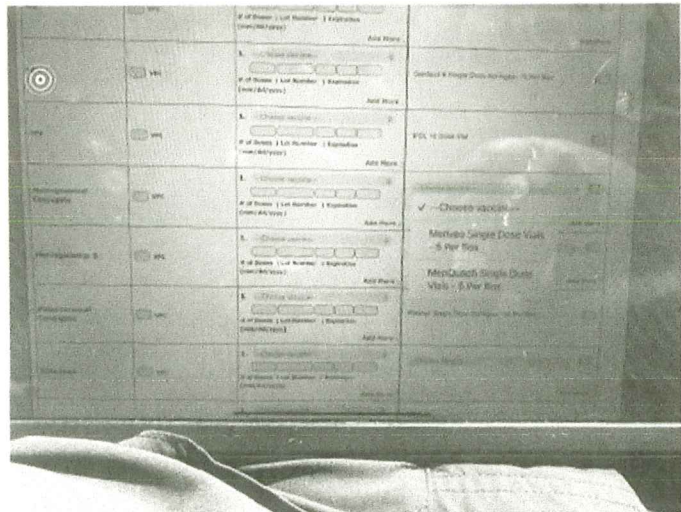
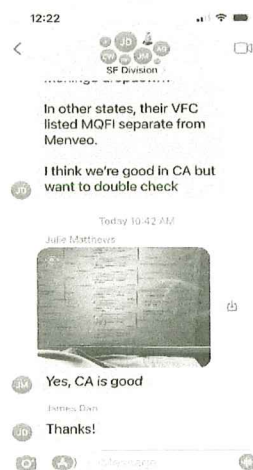
54. Specifically, Dan informed Relator and all other Northern California sales representatives the VFC PIN required to log into the EZIZ provider portal was the same as the CDC Report Account Numbers. The Zip Code for the providers was also provided by the CDC Report.



55. Dan instructed Relator and all other Northern California sales representatives to login to EZIZ provider portal using VFC providers' unique PINs—indeed to impersonate the VFC provider—and to find out which VFC providers were using GSK's Pediarix over Defendants' products. Dan then instructed Relator

1 and all other Northern California sales representatives to focus their sales efforts at
 2 aggressively “converting” those VFC providers using GSK’s Pediarix to purchase
 3 Defendants’ products instead, specifically Vaxelis. SANOFI, conspiring with its
 4 manufacturing and marketing partner MERCK, induced its sales force to engage in
 5 fraud for anticompetitive purposes.

6 56. From April 2022 to the present, Relator observed on numerous
 7 occasions other SANOFI sales representatives log on to EZIZ as if they were a
 8 VFC provider, without that VFC provider’s knowledge or consent, and review the
 9 vaccine order history. The Northern California sales representatives who have
 10 accessed, and continue to access the EZIZ provider portal, have done so at the
 11 behest of Defendants’ management level employees, including but not limited to,
 12 Dan and other District Sales Managers overseeing sales districts in California.

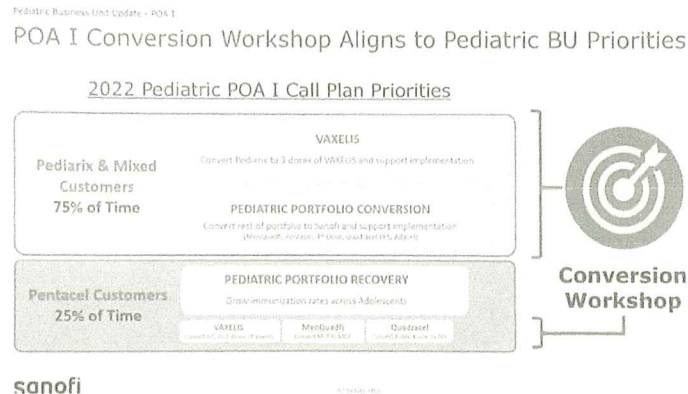


23 57. In approximately February 2022, SANOFI initiated a campaign called
 24 the “California Go Green Kickoff Call” to drive down the market share of GSK’s
 25 Pediarix and drive up the market share of Defendants’ Vaxelis.

26 58. SANOFI sends regular “Go Green” updates to its sales representatives,
 27 including Relator, reporting on its market share relative to its competitor, GSK, and
 28 explicitly encouraging continued antitrust activities, enabled by Defendants’ illegal

1 use of state-monitored vaccine ordering data.

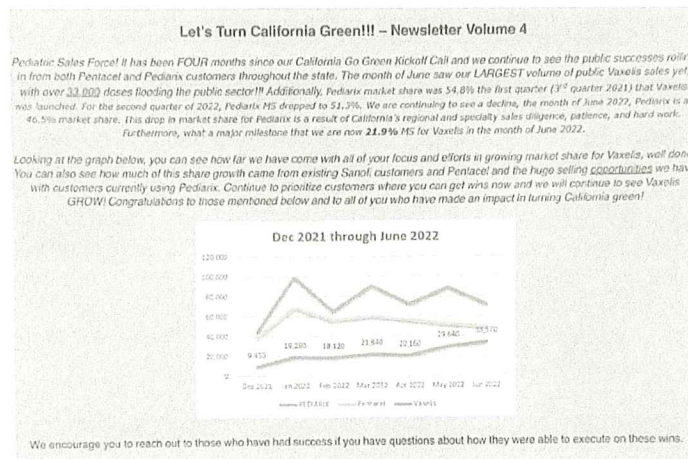
2 59. SANOFI, in collusion with its manufacturing and marketing partner
3 MERCK, designed and organized trainings for its sales representatives on “Pediarix
4 Conversion,” *i.e.*, targeting sales efforts on VFC providers that have historically
5 ordered Pediarix, to convince them to switch to Vaxelis.



14 60. Moreover, SANOFI has incentivized and impliedly required all
15 Northern California sales associates, including Relator, to use the EZIZ provider
16 portal data to sell Vaxelis. Specifically, SANOFI offers monetary bonuses for
17 “Pediarix Conversions” that directly correlate to the change in market share
18 percentages. However, even if Relator met 100% of his sales goals, if Relator did
19 not drive down the market share of Pediarix through conversions, he did not receive
20 full commission payment. Thus, SANOFI effectively requires the illegal use of
21 EZIZ provider portal data and “Pediarix Conversions” by Relator and its other sales
22 representatives.

23 61. Through this illegal scheme, and as reported by “Go Green” updates,
24 Defendants have been able to consistently increase the market share of Vaxelis
25 while also decreasing the market share of Pediarix. In approximately ten months,
26 since the Vaxelis launch, the Pediarix market share dropped from 54.8% to 46.5%.
27 In this same time period, Vaxelis took over nearly a quarter of the market share.
28 SANOFI’s Pentacel consistently occupies approximately another quarter of the

market share.



62. As a result of Defendants' illicit practices, they are on their way to establishing market dominance. Specifically, SANOFI is explicitly engaging in conversion practices to drive out its largest competitor, GSK's Pediarix.

63. By occupying a majority of the childhood vaccine market, Defendants simultaneously augment their negotiating power with the HHS Secretary for annual VFC purchasing contracts. As a result, the Federal government is forced to pay higher costs for necessary vaccines to distribute to the children of the country's most vulnerable populations every time it purchases supply for the VFC program.

64. More directly, Defendants' illicit practices cause more government funds to flow their way for each extra Vaxelis sale made in its takeover of the market.

65. Defendants induced HHS to enter into a purchasing contract for vaccines by predicating their bargaining position on false information and fraudulent pricing. By fraudulently inducing the government to contract for the production of Vaxelis, a more expensive vaccine alternative, each subsequent claim or contract results in additional monetary loss to the government. For the period of April 1, 2022 to March 31, 2023 alone, HHS paid \$437,014,442 to SANOFI and \$1,993,114,234 to MERCK under a VFC purchasing contract.

66. Relator is informed and believes, and thereon alleges, that Defendants

1 are required to expressly certify, as a condition of contracting with the HHS
2 Secretary, that they have engaged in good-faith negotiations in compliance with all
3 Federal laws for the VFC purchasing contract. Relator is informed and believes that
4 Defendants made such certification prior to contracting with HHS.

5 67. Relator is further informed and believes, and thereon alleges, that
6 Defendants are required, as a condition of contracting with the HHS Secretary, to
7 expressly certify that they have engaged in full and open competition in compliance
8 with all Federal laws with other similarly-situated manufacturers. Relator is
9 informed and believes that Defendants made such certification prior to contracting
10 with HHS.

11 68. Furthermore, the act of negotiating with HHS impliedly communicates
12 compliance with all Federal laws that are a precondition to payment – *i.e.*, the act of
13 coming to the negotiating table and engaging in discussions impliedly certifies that
14 all parties are coming to the table with equal bargaining power as a result of fair
15 market activities.

16 69. However, despite their certifications to HHS, Defendants illegally
17 hacked into the California-run VFC provider portal and violated anti-trust laws to
18 gain market dominance and increased bargaining power – ultimately to the expense
19 of the Federal government and children in need.

20 70. Defendants made further false statements to the state of California,
21 and by extension the United States government each time they logged into EZIZ
22 under false pretenses. Those misrepresentations caused the submission of claims to
23 the government and caused the payment of government monies to Defendants as
24 additional sales were generated. The false statements also directly resulted in
25 valuable sales data be acquiring by Defendants, which itself constitutes a thing of
26 value, from the government, obtained under false pretenses.

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COUNT ONE

Violations of Federal False Claims Act

31 U.S.C. § 3729, *et seq.*

71. Relator incorporates and realleges all the facts and allegations set forth above.

72. This Count is brought by Relator in the name of the United States under the *qui tam* provisions of 31 U.S.C. § 3730 for Defendants' violations of 31 U.S.C. § 3729 against Defendants SANOFI and MERCK.

73. Defendants SANOFI and MERCK, by virtue of the above-described acts, among others, knowingly or in reckless disregard or deliberate ignorance of the truth or falsity of the information involved, made, used, caused to be made or caused to be used, false or fraudulent statements in [], in violation, *inter alia*, of 31 U.S.C. § 3729(a)(1).

74. Defendants SANOFI and MERCK defrauded the United States by knowingly, falsely, and intentionally accessing unauthorized data regarding state vaccine sales in order to gain an unfair advantage over their competition and obtain a larger share of the market when contracting with the Secretary of Health and Human Services for the manufacture of vaccines.

75. By engaging in the above conduct, Defendants committed fraud in the inducement, made material misrepresentations and certifications in contracting with the Secretary of HHS, and submitted factually false claims in order to obtain Federal funds.

76. The false or fraudulent claims to the United States were material.

77. Plaintiff United States, being unaware of the falsity of the claims and/or statements made by Defendants, and in reliance on the accuracy thereof, paid federal funds to Defendants.

78. The United States has sustained damages because of each of Defendants' actions.

1 WHEREFORE, Realtor requests relief as hereafter provided.

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PRAYER FOR RELIEF

WHEREFORE, Relator respectfully prays that with respect to violations of the Federal False Claims Act, Count One, that judgment be entered against Defendant as follows:

- a. That Defendants SANOFI and MERCK be found to have violated and be enjoined from future violations of the Federal False Claims Act, 31 U.S.C. §§ 3729-32;
- b. That Defendants SANOFI and MERCK not less than \$5,000 and not more than \$10,000.00 for each violation of 31 U.S.C. § 3729, plus three times the amount of damages the United States has sustained because of Defendants' actions;
- c. That Relator be awarded the maximum "Relator's share" allowed pursuant to 31 U.S.C. § 3730(d), and all relief to which Relator is entitled to pursuant to statute, including costs and attorney's fees; and
- d. That the United States and the Relator be awarded such other relief as the Court deems just and proper, including reasonable attorney's fees and costs.

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Dated: February 21, 2023

Respectfully Submitted,



Rob Hennig (State Bar No. 174646)
Sam Brown (State Bar No. 308558)
Adrian Hernandez (State Bar No. 325532)
Helen You (State Bar. No. 329057)
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Attorney for Relator WAYNE HARRINGTON

DEMAND FOR JURY TRIAL

Relator, on behalf of himself and the United States, demands a jury trial on all claims alleged herein. Plaintiff demands trial by jury in this matter.

Dated: February 21, 2023

Respectfully Submitted,


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